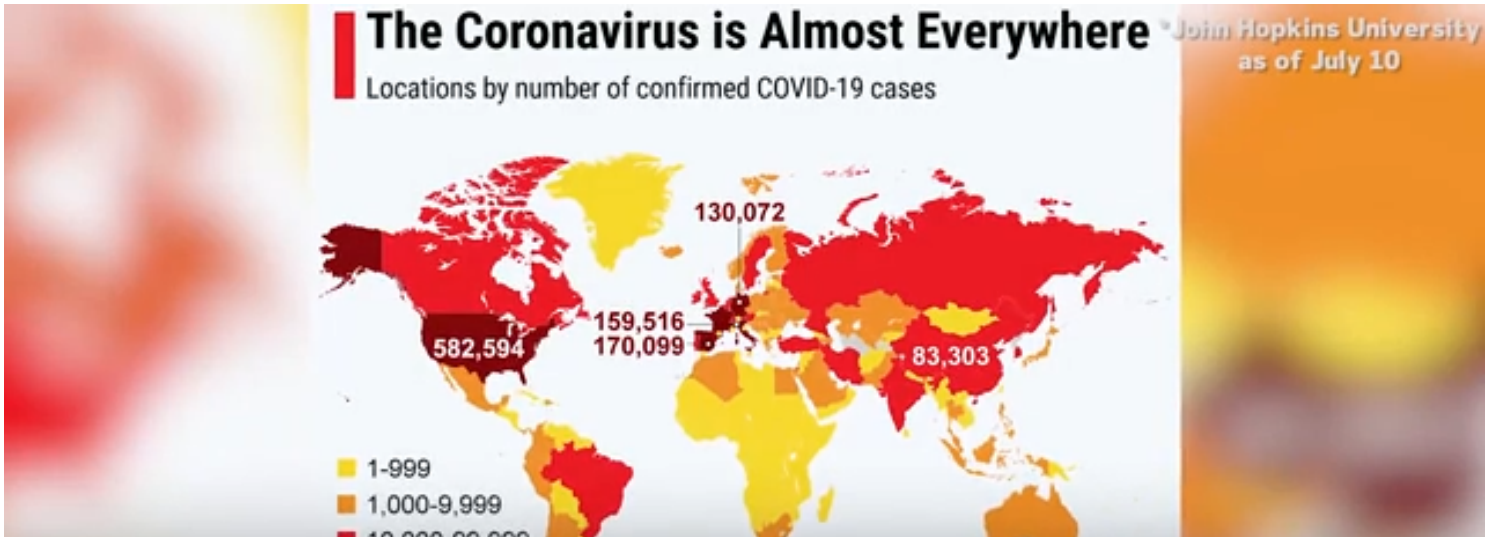
OPINION

The Key to Defeating COVID-19 Already Exists. We Need to Start Using It | Opinion

HARVEY A. RISCH, MD, PHD, *PROFESSOR OF EPIDEMIOLOGY, YALE SCHOOL OF PUBLIC HEALTH*

ON 7/23/20 AT 7:00 AM EDT



OPINION CORONAVIRUS HEALTH AND MEDICINE MEDICINE FDA

As professor of epidemiology at Yale School of Public Health, I have authored over 300 peer-reviewed publications and currently hold senior positions on the editorial boards of several leading journals. I am usually accustomed to advocating for positions within the mainstream of medicine, so have been flummoxed to find that, in the midst of a crisis, I am fighting for a treatment that the data fully support but which, for reasons having nothing to do with a correct understanding of the science, has been pushed to the sidelines. As a result, tens of thousands of patients with COVID-19 are dying unnecessarily. Fortunately, the situation can be reversed easily and quickly.

I am referring, of course, to the medication hydroxychloroquine. When this inexpensive oral medication is given very early in the course of illness, before the virus has had time to multiply beyond control, it has shown to be highly effective, especially when given in combination with the antibiotics azithromycin or doxycycline and the nutritional supplement zinc.

On May 27, I published an article in the *American Journal of Epidemiology* (*AJE*) entitled, "Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients that Should be Ramped-Up Immediately as Key to the Pandemic

Crisis." That article, published in the world's leading epidemiology journal, analyzed five studies, demonstrating clear-cut and significant benefits to treated patients, plus other very large studies that showed the medication safety.

Physicians who have been using these medications in the face of widespread skepticism have been truly heroic. They have done what the science shows is best for their patients, often at great personal risk. I myself know of two doctors who have saved the lives of hundreds of patients with these medications, but are now fighting state medical boards to save their licenses and reputations. The cases against them are completely without scientific merit.

Since publication of my May 27 article, seven more studies have demonstrated similar benefit. In a lengthy follow-up letter, also published by *AJE*, I discuss these seven studies and renew my call for the immediate early use of hydroxychloroquine in high-risk patients. These seven studies include: an additional 400 high-risk patients treated by Dr. Vladimir Zelenko, with zero deaths; four studies totaling almost 500 high-risk patients treated in nursing homes and clinics across the U.S., with no deaths; a controlled trial of more than 700 high-risk patients in Brazil, with significantly reduced risk of hospitalization and two deaths among 334 patients treated with hydroxychloroquine; and another study of 398 matched patients in France, also with significantly reduced hospitalization risk. Since my letter was published, even more doctors have reported to me their completely successful use.

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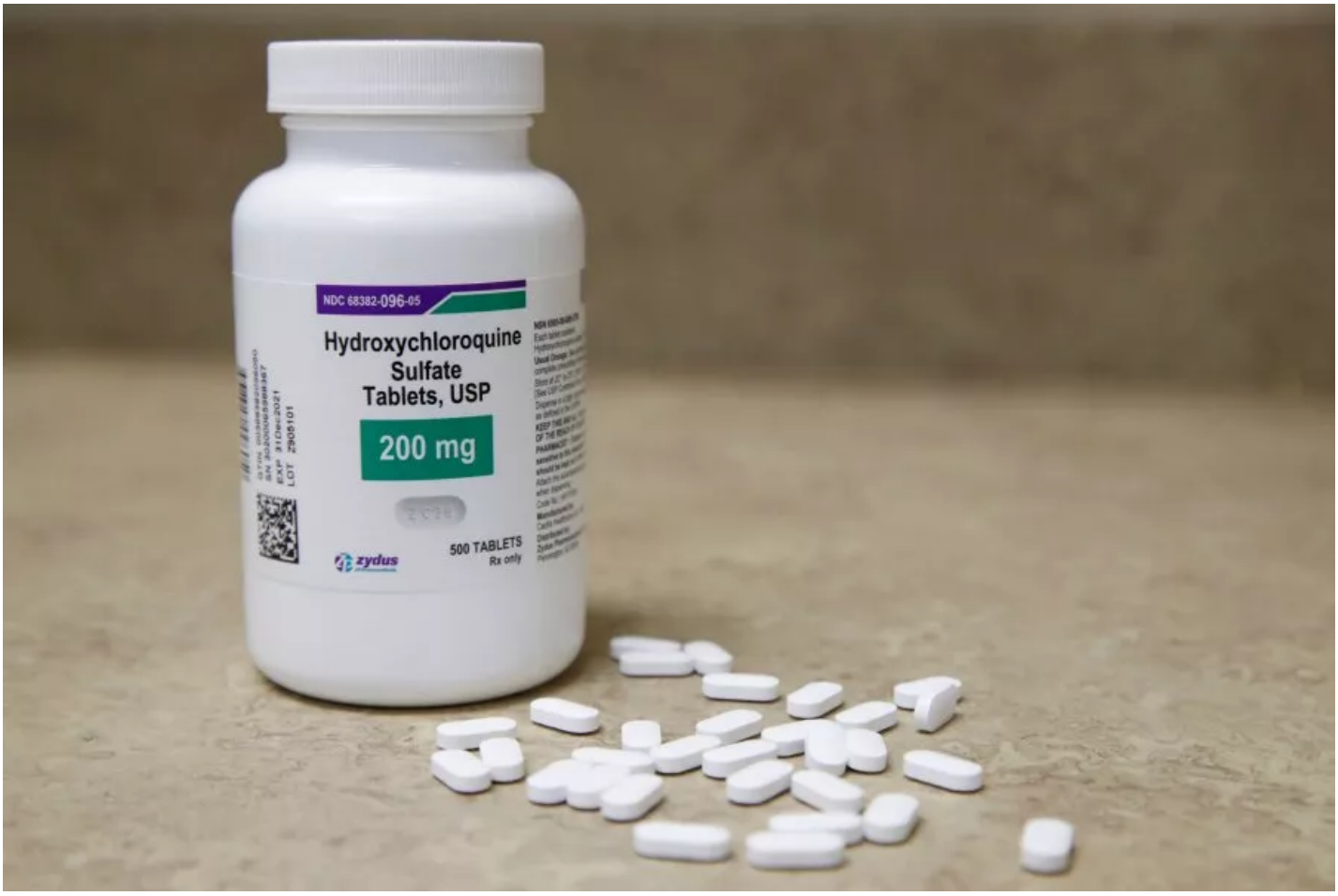


Hydroxychloroquine tablets
GEORGE FREY/AFP VIA GETTY IMAGES

A reverse natural experiment happened in Switzerland. On May 27, the Swiss national government banned outpatient use of hydroxychloroquine for COVID-19. Around June 10, COVID-19 deaths increased four-fold and remained elevated. On June 11, the Swiss government revoked the ban, and on June 23 the death rate reverted to what it had been beforehand. People who die from COVID-19 live about three to five weeks from the start of symptoms, which makes the evidence of a causal relation in these experiments strong. Both episodes suggest that a combination of hydroxychloroquine and its companion medications reduces mortality and should be immediately adopted as the new standard of care in high-risk patients.

Why has hydroxychloroquine been disregarded?

First, as all know, the medication has become highly politicized. For many, it is viewed as a marker of political identity, on both sides of the political spectrum. Nobody needs me to remind them that this is not how medicine should proceed. We must judge this medication strictly on the science. When doctors graduate from medical school, they formally promise to make the health and life of the patient their first consideration, without biases of race, religion, nationality, social standing—or political affiliation. Lives must come first.

Second, the drug has not been used properly in many studies. Hydroxychloroquine has shown major success when used early in high-risk people but, as one would expect for an antiviral, much less success when used late in the disease course. Even so, it has demonstrated significant benefit in large hospital studies in Michigan and New York City when started within the first 24 to 48 hours after admission.

In fact, as inexpensive, oral and widely available medications, and a nutritional supplement, the combination of hydroxychloroquine, azithromycin or doxycycline, and zinc are well-suited for early treatment in the outpatient setting. The combination should be prescribed in high-risk patients immediately upon clinical suspicion of COVID-19 disease, without waiting for results of testing. Delays in waiting before starting the medications can reduce their efficacy.

Third, concerns have been raised by the FDA and others about risks of cardiac arrhythmia, especially when hydroxychloroquine is given in combination with azithromycin. The FDA based its comments on data in its FDA Adverse Event Reporting System. This reporting system captured up to a thousand cases of arrhythmias attributed to hydroxychloroquine use. In fact, the number is likely higher than that, since the reporting system, which requires physicians or

patients to initiate contact with the FDA, appreciably undercounts drug side effects.

But what the FDA did not announce is that these adverse events were generated from tens of millions of patient uses of hydroxychloroquine for long periods of time, often for the chronic treatment of lupus or rheumatoid arthritis. Even if the true rates of arrhythmia are ten-fold higher than those reported, the harms would be minuscule compared to the mortality occurring right now in inadequately treated high-risk COVID-19 patients. This fact is proven by an Oxford University study of more than 320,000 older patients taking both hydroxychloroquine and azithromycin, who had arrhythmia excess death rates of less than 9/100,000 users, as I discuss in my May 27 paper cited above. A new paper in the *American Journal of Medicine* by established cardiologists around the world fully agrees with this.

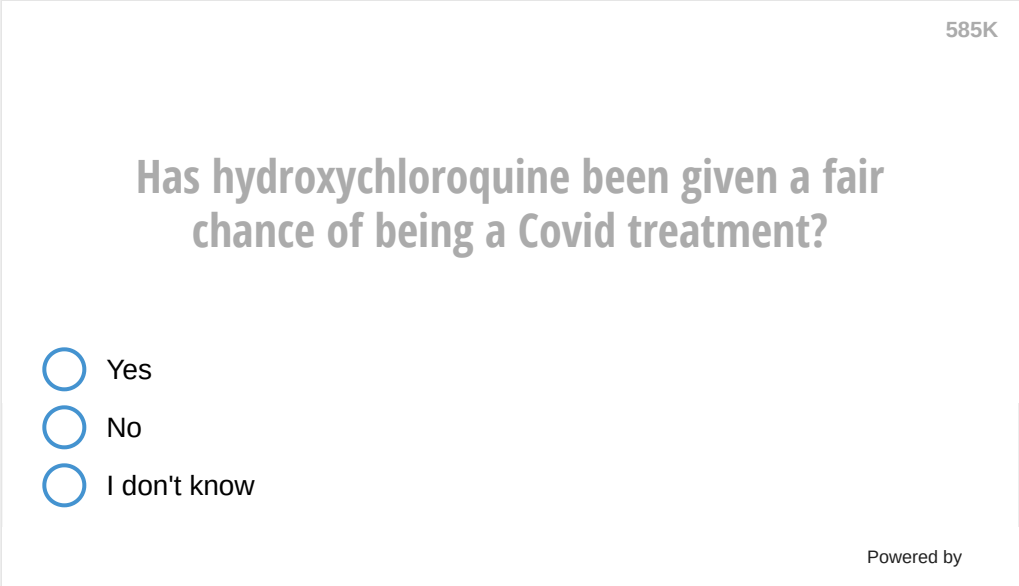
In the future, I believe this misbegotten episode regarding hydroxychloroquine will be studied by sociologists of medicine as a classic example of how extra-scientific factors overrode clear-cut medical evidence. But for now, reality demands a clear, scientific eye on the evidence and where it points. For the sake of high-risk patients, for the sake of our parents and grandparents, for the sake of the unemployed, for our economy and for our polity, especially those disproportionally affected, we must start treating immediately.

Harvey A. Risch, MD, PhD, is professor of epidemiology at Yale School of Public Health.

The views expressd in this article are the writer's own.

My original article in the *AJE* is available free online, and I encourage readers—especially physicians, nurses, physician assistants and associates, and respiratory therapists—to search the title and read it. My follow-up letter is linked there to the original paper.

Beyond these studies of individual patients, we have seen what happens in large populations when these drugs are used. These have been "natural experiments." In the northern Brazil state of Pará, COVID-19 deaths were increasing exponentially. On April 6, the public hospital network purchased 75,000 doses of azithromycin and 90,000 doses of hydroxychloroquine. Over the next few weeks, authorities began distributing these medications to infected individuals. Even though new cases continued to occur, on May 22 the death rate started to plummet and is now about one-eighth what it was at the peak.



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Observer
26 July, 2020

It is discouraging to see political partisanship enter the arena of medical decisions. Let's hope that the effectiveness or ineffectiveness of hydroxychloroquine can be established soon. Thousands of lives may depend on it.

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man00ver
23 July, 2020

Also worth noting: the American Heart Association published a moderately large retrospective review on 29-April, looking for heart problems in COVID-19 patients treated with stand-alone Chloroquine, or with HCQ (either stand-alone or combined with Azithromycin). They didn't find any TdP cardiac deaths (the rumored "sudden death" syndrome), and though they found some QT Interval elongation, it was mild enough that therapy didn't have to be discontinued for any patients. You can find the study at ahajournals-dot-org under the title, "Effect of Chloroquine, Hydroxychloroquine, and Azithromycin on the Corrected QT Interval in Patients With SARS-CoV-2 Infection." Curiously, there was almost no media coverage of their findings.

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D. Goldin, PhD
23 July, 2020

When Prof. Risch discussed how HCQ "has not been used properly in many studies", I am surprised he failed to mention that the dose those studies used was inappropriately high, in fact TOXIC. This medicine has been widely used around the globe since 1955 and its safety profile is well known. In proper doses, it is safer than Tylenol or Motrin. It is not clear why the study designers chose to use a toxic dose. When "this misbegotten episode" is studied by sociologists and historians, perhaps we will find out. *(Edited)*

Reply 439 23

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Daniel Connelly
23 July, 2020

Since March, the physicians and medical providers at our New Jersey internal medicine practice have been prescribing hydroxychloroquine +zinc + azithromycin or doxycycline immediately to newly diagnosed outpatient and nursing home Covid-19 patients. Diagnosis is based on symptoms and chest x-ray followed up by PCR testing for confirmation. To date, in our small sample, everyone has recovered (quickly) with no hospitalizations and no stoppage due to side effects.

Hydroxychloroquine is used during pregnancy to treat Lupus or Malaria in the mother and cardiac arrhythmia in the fetus. It is pregnancy Category D where benefits of use exceed the risk in case by case basis even though human studies have found no excess risk.

The drug combination appears both safe and effective when given early. Early, meaning with the onset of symptoms. PCR testing results can take over two weeks to return and the window of opportunity can be lost.

Reply 288 17

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Critical Thinkr

24 July, 2020

Dr. Stephen Smith (Smith Center of Infectious Disease) says dosage should be about 6.5 mg per Kg of weight. Anyone over 50 should have HCQ in their medicine cabinet; use it at first symptoms. Then go get tested, a few days can possibly save your life. If you're negative, stop taking it; if you're positive, you'll be glad you did. Many doctors will prescribe this if you ask them.

Reply 171 12

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ccrevier
24 July, 2020

This 'misbegotten episode of medical history' is actually the **second round** of misbegotten episodes within this pandemic. Dr. Paul Marik, an intensivist from the Eastern Virginia Medical School and seven other like-minded ICU docs published a bulletin to the critical care medicine community the first week in April describing their protocol. In this bulletin, they urged their fellow physicians to **ignore the advice of the FDA, NIH and the WHO to *NOT use steroids to treat COVID patients and NOT VENT these patients.*** In other words, within the first few weeks of this pandemic, these organizations had broadcasted to the entire medical community that the use of steroids in the context of very sick COVID19 patients was not to be done. Thank God that these physicians had the good sense to rely on their years of experience, knowledge of the pathophysiology of the respiratory system/immune system and the pharmacology of steroids and saved their patients' lives. Meanwhile, their voices were ignored and American cities scurried around to build more ventilator capacity. Hundreds, maybe thousands of people died because dexamethasone was not widely adopted until after the Recovery Trial, reported June 19, **7 weeks later. Marik, et al., Risch and other independent thinking physicians will be the heroes when the medical history is written. Thank you for your courage Dr. Risch. Carol Crevier, RN MPH**

Reply 213 22

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LUCIDANDBLACK
24 July, 2020

Studying the following website, c19study dotcom, makes it very clear what is occurring. (Click on the graph to toggle between webpage.) As Dr. Zelenko has stated, "People are not dying from COVID, they are dying from ineffectual political leadership."

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Spanky Logica
24 July, 2020

Newswk slipped and published something accurate. I'm sure the editors had no idea what this implies.

Reply 279 37

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Mike B
29 July, 2020

My own doctor has treated over 100 patients using the hydroxy, azithromycin and zinc protocol. According to him all are well except one who still has symptoms. It's really unfortunate that any positive news about this is suppressed by the media and some have even resorted to calling the drug dangerous. It's been safely used by tens of millions of people for over 50 years so how can it now suddenly be classed as dangerous? Can anyone explain why the Central African countries where this drug is widely used as a prophylactic for malaria have extremely low incidence of Covid? Just compare Brazil and Nigeria, both 200 m + people, both with crowded living conditions but vastly different numbers of infections as well as vastly different prevalence of malaria. Nigeria now averaging 600 infections a day, Brazil at 45,000. Ethiopia with 100 m population with daily infections currently at 600 a day. India and Brazil are on fire (low malaria levels) yet the entirety of central Africa plus other malaria areas like Thailand and Vietnam are barely affected. If we find this global catastrophe could have been prevented by a 10cent pill then those who suppressed free speech and healthy debate and trial of this treatment should be held accountable. FYI I have no political bias - I just want to see everyday people freed from the fear, terror and economic disaster that has needlessly been forced upon us. If it's simply to win an election then God help us all.

Reply 20

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man00ver
23 July, 2020

Please check on worldometer to compare the deaths-per-million rate for India, a densely populated country bordering China where HCQ is in wide use as both treatment and preventative for COVID-19. While you're there, look at deaths-per-million in the African nations, who have HCQ available over the counter, and who listen carefully to African-born French epidemiologist Dr. Didier Raoult (Trump's inspiration regarding HCQ for COVID-19). Then look at the deaths-per-million rate for the USA. The data on its effectiveness look compelling to me.

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U.S.

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